

Remarks

Claims 1-4, 22-26, 41, 42, 59-63, 65-69, and 72-77 were pending. By this amendment, no claims are added, and claims 3, 22, 41, 42, 59 and 69 are cancelled without prejudice to prosecution in a future application. Therefore, claims 1, 2, 4, 23-26, 60-63, 65-68 and 72-77 are now pending.

Claims 23-25, 60-63, and 65-68 were amended due to the cancellation of claim 22.

Support for the amendments to the claims can be found throughout the specification, for example:

Claim 1: claims 22, 41, 42, and 59

Claims 72 and 75: claim 42

No new matter is added by these amendments, and no amendments were made to distinguish prior art.

Telephone interview

Applicants thank Examiner Marvich and her supervisor Dan Sullivan for the courtesy of a telephone interview with Applicants' representative Sheree Lynn Rybak, Ph.D. on September 8, 2005. During this interview, all of the pending rejections were discussed.

With regards to the 35 U.S.C. § 112, first paragraph rejection of claim 69, the Examiners asserted that the specification did not clearly indicate that the C-terminal 211 amino acids were intended for therapeutic use. Applicants' representative noted that "fragments" of EDA1-II as therapeutic agents are disclosed, and that one particular fragment disclosed in the application is the C-terminal 211 amino acids. Agreement on this issue was not reached.

With regards to the 35 U.S.C. § 112, first paragraph enablement rejection of all of the pending claims, the Examiners asserted that the reason for the rejection is that although Applicants have shown that EDA1-II can correct at least some of the ectodermal defects in Tabby mice, there is no data in a more generic animal model, which would indicate that EDA1-II

activity could be used generally to promote growth of ectodermal structures. The Examiners agreed that the claims would likely be allowed if the limitations of claim 42 were included in the independent claim.

With regards to the 35 U.S.C. § 102(e) rejection of claims 1, 22 and 24-26, Applicants representative noted that claims 22 and 24-26 include particular SEQ ID NOS, which are not disclosed in the references cited. In view of this information, the Examiners agreed to reconsider this rejection.

35 U.S.C. § 112, first paragraph

Claim 69 is rejected under 35 U.S.C. § 112, first paragraph, on the grounds that this claim does not comply with the written description requirement. Although applicants respectfully disagree, in order to expedite prosecution, claim 69 is cancelled without prejudice to prosecution in a future application.

1-4, 22-26, 41, 42, 59-69, and 72-77 are rejected under 35 U.S.C. § 112, first paragraph, on the grounds that these claim do not comply with the enablement requirement. Although Applicants respectfully disagree, claim 1 has been amended to clarify that the method is a method of increasing hair follicle development, sweat gland development, or both, in a subject having X-linked hypohidrotic ectodermal dysplasia (XLHED) or autosomal hypohidrotic ectodermal dysplasia (HED), by administration an amount of EDA1-II protein that includes at least 153 amino acids of SEQ ID NO: 2. As Applicants have shown that administration of an EDA1-II fragment can promote hair follicle development and sweat gland development in an animal model of ectodermal dysplasia, using the methods disclosed in the application, the pending claims are fully enabled.

In view of these amendments, and the Rule 132 Declarations previously presented, Applicants request that the 35 U.S.C. § 112, first paragraph rejections be withdrawn.

35 U.S.C. § 102(e)

Claims 1, 22 and 24-26 are rejected under 35 U.S.C. § 102(e) as anticipated by Mathews et al. (U.S. 6,159,462) as evidenced by Durmowicz et al. (Gene, 285:203-11, 2002). Applicants respectfully disagree and request reconsideration.

Claim 1 specifies that the EDA1-II protein comprises at least 153 amino acids of SEQ ID NO: 2. As neither Mathews *et al.* (U.S. 6,159,462) nor Durmowicz *et al.* disclose at least 153 amino acids from SEQ ID NO: 2, the claims are not anticipated by these documents. Applicants therefore request that the 35 U.S.C. § 102(e) rejection be withdrawn.

It is believed that the amendments place this application in condition for allowance. If there are any minor issues that need to be resolved prior to issuing a Notice of Allowance, the Examiner is invited to telephone the undersigned.

Respectfully submitted,

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